

AMENDED IN SENATE MAY 26, 2006

SENATE BILL

No. 1748

Introduced by Senator Figueroa

February 24, 2006

An act to amend ~~Section~~ *Sections 124977 and 125001* of the Health and Safety Code, relating to public health, *and making an appropriation therefor.*

LEGISLATIVE COUNSEL'S DIGEST

SB 1748, as amended, Figueroa. Cystic fibrosis *and biotinidase*: newborn screening.

Existing law, the Hereditary Disorders Act, among other provisions, declares the intent of the Legislature that the state's hereditary disorders program activities are to be fully supported by fees collected for services provided by the program, unless otherwise provided. Existing law requires the State Department of Health Services to charge a fee to all payers for any tests or activities performed pursuant to provisions relating to genetic disorder prevention services, including the Hereditary Disorders Act. Existing law requires that any fee charged for screening and follow-up services provided to Medi-Cal eligible persons, health care service plan enrollees, or persons covered by disability insurance policies are to be paid directly to the Genetic Disease Testing Fund, a continuously appropriated fund, to be used for the purposes of the Hereditary Disorders Act.

This bill would authorize the expenditure of funds from the Genetic Disease Testing Fund for the expansion of the Genetic Disease Branch Screening Information System through the amendment of the Genetic Branch Screening Information Systems contracts, and would

exempt that expansion from specified requirements governing public contracts and contracts for information technology projects. By expanding the purposes for which moneys from the fund may be expended, the bill would make an appropriation.

Existing law requires the ~~State Department of Health Services~~ *department* to establish a program for the development, provision, and evaluation of genetic disease testing, and authorizes the department to provide laboratory testing facilities or make grants to, contract with, or make payments to, any laboratory that it deems qualified and cost-effective to conduct testing or with any metabolic specialty clinic to provide necessary treatment with qualified specialists. Existing law requires the department to expand statewide screening of newborns to include tandem mass spectrometry screening for fatty acid oxidation, amino acid, and organic acid disorders, and congenital adrenal hyperplasia, and requires the department to report to the Legislature regarding the progress of the program on or before July 1, 2006.

This bill would additionally require the department to expand statewide screening of newborns to include *biotinidase and* cystic fibrosis screening to detect *biotinidase and* cystic fibrosis as soon as possible. The bill would require the department, not later than July 1, 2007, to report to the Legislature on the progress of the program with respect to newborn screening for *biotinidase and* cystic fibrosis, including an estimate of the costs for screening, follow-up, and treatment as compared to costs and morbidity averted by this testing under the program. *The bill would make the expanded statewide screening of newborns for these conditions contingent upon the provision of funding in the Budget Act.*

Vote: majority. Appropriation: ~~no~~ yes. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 **SECTION 1.** *Section 124977 of the Health and Safety Code is*
- 2 *amended to read:*
- 3 124977. (a) It is the intent of the Legislature that, unless
- 4 otherwise specified, the program carried out pursuant to this
- 5 chapter be fully supported from fees collected for services
- 6 provided by the program.
- 7 (b) (1) The department shall charge a fee to all payers for any
- 8 tests or activities performed pursuant to this chapter. The amount

1 of the fee shall be established by regulation and periodically
 2 adjusted by the director in order to meet the costs of this chapter.
 3 Notwithstanding any other provision of law, any fees charged for
 4 prenatal screening and followup services provided to persons
 5 enrolled in the Medi-Cal program, health care service plan
 6 enrollees, or persons covered by health insurance policies, shall
 7 be paid in full directly to the Genetic Disease Testing Fund,
 8 subject to all terms and conditions of each enrollee's or insured's
 9 health care service plan or insurance coverage, whichever is
 10 applicable, including, but not limited to, copayments and
 11 deductibles applicable to these services, and only if these
 12 copayments, deductibles, or limitations are disclosed to the
 13 subscriber or enrollee pursuant to the disclosure provisions of
 14 Section 1363.

15 (2) The department shall expeditiously undertake all steps
 16 necessary to implement the fee collection process, including
 17 personnel, contracts, and data processing, so as to initiate the fee
 18 collection process at the earliest opportunity.

19 (3) The director shall convene, in the most cost-efficient
 20 manner and using existing resources, a working group comprised
 21 of health insurance, health care service plan, hospital, consumer,
 22 and department representatives to evaluate newborn and prenatal
 23 screening fee billing procedures, and recommend to the
 24 department ways to improve these procedures in order to
 25 improve efficiencies and enhance revenue collections for the
 26 department and hospitals. In performing its duties, the working
 27 group may consider models in other states. The working group
 28 shall make its recommendations by March 1, 2005.

29 (4) Effective for services provided on and after July 1, 2002,
 30 the department shall charge a fee to the hospital of birth, or, for
 31 births not occurring in a hospital, to families of the newborn, for
 32 newborn screening and followup services. The hospital of birth
 33 and families of newborns born outside the hospital shall make
 34 payment in full to the Genetic Disease Testing Fund. The
 35 department shall not charge or bill Medi-Cal beneficiaries for
 36 services provided under this chapter.

37 (c) (1) The Legislature finds that timely implementation of
 38 changes in genetic screening programs and continuous
 39 maintenance of quality statewide services requires expeditious
 40 regulatory and administrative procedures to obtain the most

1 cost-effective electronic data processing, hardware, software
2 services, testing equipment, and testing and followup services.

3 (2) The expenditure of funds from the Genetic Disease Testing
4 Fund for these purposes shall not be subject to Section 12102 of,
5 and Chapter 2 (commencing with Section 10290) of Part 2 of
6 Division 2 of, the Public Contract Code, or to Division 25.2
7 (commencing with Section 38070). The department shall provide
8 the Department of Finance with documentation that equipment
9 and services have been obtained at the lowest cost consistent
10 with technical requirements for a comprehensive high-quality
11 program.

12 (3) The expenditure of funds from the Genetic Disease Testing
13 Fund for implementation of the Tandem Mass Spectrometry
14 screening for fatty acid oxidation, amino acid, and organic acid
15 disorders, and screening for congenital adrenal hyperplasia may
16 be implemented through the amendment of the Genetic Disease
17 Branch Screening Information System contracts and shall not be
18 subject to Chapter 3 (commencing with Section 12100) of Part 2
19 of Division 2 of the Public Contract Code, Article 4
20 (commencing with Section 19130) of Chapter 5 of Part 2 of
21 Division 5 of Title 2 of the Government Code, and any policies,
22 procedures, regulations or manuals authorized by those laws.

23 (4) (A) *Funds from the Genetic Disease Testing Fund may be*
24 *expended to expand the Genetic Disease Branch Screening*
25 *Information System through the amendment of the Genetic*
26 *Disease Branch Screening Information System contracts, and*
27 *shall not be subject to Chapter 3 (commencing with Section*
28 *12100) of Part 2 of Division 2 of the Public Contract Code,*
29 *Article 4 (commencing with Section 19130) of Chapter 5 of Part*
30 *2 of Division 5 of Title 2 of the Government Code, and any*
31 *policies, procedures, regulations, or manuals authorized by those*
32 *laws, as they relate to the approval of information technology*
33 *projects, or approval of increases in the duration or costs of*
34 *information technology projects.*

35 (B) *Subparagraph (A) shall apply only to the design,*
36 *development, and implementation of the expansion, and to the*
37 *ongoing maintenance of the Genetic Disease Branch Screening*
38 *Information System, once the expansion is implemented.*

39 (d) (1) The department may adopt emergency regulations to
40 implement and make specific this chapter in accordance with

Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. For the purposes of the Administrative Procedure Act, the adoption of regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, these emergency regulations shall not be subject to the review and approval of the Office of Administrative Law. Notwithstanding Section 11346.1 and Section 11349.6 of the Government Code, the department shall submit these regulations directly to the Secretary of State for filing. The regulations shall become effective immediately upon filing by the Secretary of State. Regulations shall be subject to public hearing within 120 days of filing with the Secretary of State and shall comply with Sections 11346.8 and 11346.9 of the Government Code or shall be repealed.

(2) The Office of Administrative Law shall provide for the printing and publication of these regulations in the California Code of Regulations. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the regulations adopted pursuant to this chapter shall not be repealed by the Office of Administrative Law and shall remain in effect until revised or repealed by the department.

(3) The Legislature finds and declares that the health and safety of California newborns is in part dependent on an effective and adequately staffed genetic disease program, the cost of which shall be supported by the fees generated by the program.

SECTION 1.

SEC. 2. Section 125001 of the Health and Safety Code is amended to read:

125001. (a) The department shall establish a program for the development, provision, and evaluation of genetic disease testing, and may provide laboratory testing facilities or make grants to, contract with, or make payments to, any laboratory that it deems qualified and cost-effective to conduct testing or with any metabolic specialty clinic to provide necessary treatment with qualified specialists. The program shall provide genetic

1 screening and followup services for persons who have the
2 screening.

3 (b) The department shall expand statewide screening of
4 newborns to include tandem mass spectrometry screening for
5 fatty acid oxidation, amino acid, and organic acid disorders,
6 congenital adrenal hyperplasia, *biotinidase*, and cystic fibrosis, as
7 soon as possible. The department shall provide information with
8 respect to these disorders and available testing resources to all
9 women receiving prenatal care and to all women admitted to a
10 hospital for delivery. If the department is unable to provide this
11 statewide screening by August 1, ~~2005~~ 2007, the department
12 shall temporarily obtain these testing services through a
13 competitive bid process from one or more public or private
14 laboratories that meet the department's requirements for testing,
15 quality assurance, and reporting. If the department determines
16 that contracting for these services is more cost-effective, and
17 meets the other requirements of this chapter, than purchasing the
18 tandem mass spectrometry equipment themselves, the department
19 shall contract with one or more public or private laboratories.

20 (c) (1) The department shall report to the Legislature
21 regarding the progress of the program on or before July 1, 2006.
22 The report shall include the costs for screening, follow-up, and
23 treatment as compared to costs and morbidity averted for each
24 condition tested for in the program.

25 (2) The department shall report to the Legislature regarding
26 the progress of the program with regard to implementing
27 newborn screening for *biotinidase* and cystic fibrosis required
28 pursuant to subdivision (b) on or before July 1, 2007. The report
29 shall include the costs for screening, follow-up, and treatment as
30 compared to costs and morbidity averted by this testing under the
31 program.

32 (d) *The expansion of statewide screening of newborns for*
33 *biotinidase and cystic fibrosis, as provided in subdivision (b),*
34 *shall be contingent on the provision of funding for those*
35 *purposes in the Budget Act.*